K032129

JUL 17 2003

Attachment 6
510(k) Summary of Safety and Effectiveness
July 9, 2003

A. GENERAL INFORMATION

Submitter's Name:	Radius Medical Technologies, Inc.
Address:	15 Craig Road Acton, MA 01720
Contact Person:	Maureen A. Finlayson
Device Generic Name:	PTCA Guidewire
Device Trade Name:	Radius .018 Cougar Wire
Classification Name:	Wire, Guide, Cardiovascular (74DQX)

B. INDICATIONS

The Radius .018 Cougar Wire is intended to facilitate the placement of balloon dilitation catheters during PTCA and/or PTA. The **Radius .018 Cougar Wires** are compatible with all currently approved and marketed PTCA/PTA balloon catheters which are labeled for use with an .018 guidewire.

C. DESCRIPTIVE CHARACTERISTICS

The **Radius .018 Cougar Wire** is constructed from a composite stainless steel and Nitinol core to which a coil is attached to the tapered distal section. The proximal section of the wire is coated with PTFE, and the distal coil portion of the wire is hydrophilic coated. The device is packaged in a protective hoop sealed into a Tyvek/mylar pouch, and is sterilized using ETO gas.

D. COMPARATIVE INFORMATION

The **Radius .018 Cougar Wire** is substantially equivalent to the currently marketed **Radius Cougar Guidewire** (K011287).

E. PERFORMANCE TESTING

The following in vitro performance tests were performed on the **Radius .018 Cougar Wire**:

1. Tensile Strength
2. Torque Strength
3. Torqueability
4. Tip Flexibility
5. Coating Adherence/Integrity

CONCLUSION:

Based on the indications for use, technological characteristics, and safety and performance testing, the proposed **Radius .018 Cougar Wire** meets the minimum requirements that are considered adequate for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2003

Radius Medical Technologies, Inc.
c/o Debbie Iampiedro
7 Tiffany Trail
Hopkinton, MA 01748

Re: K032129
Radius 018 Cougar Wire
Regulation Number: 870.1330
Regulation Name: Cardiovascular Guidewire
Regulatory Class: Class II
Product Code: DQX
Dated: July 9, 2003
Received: July 10, 2003

Dear Ms. Iampiedro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

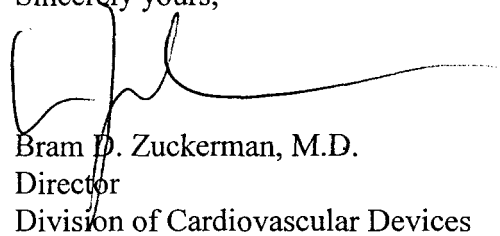
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K032129

Device Name: Radius .018 Cougar Wire

Indications For Use:

Radius .018 Cougar Wire is intended for placement of balloon dilatation catheters during PTCA and/or PTA.

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular

510(k) Number K032129